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NOTICE OF ALLOWANCE AND FEE(S) DUE

29052 7590 12/23/2010

SUTHERLAND ASBILL & BRENNAN LLP
999 PEACHTREE STREET, N.E.
ATLANTA, GA 30309

EXAMINER	
VU, QUYNH-NHU HOANG	
ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 12/23/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,897	02/20/2004	John T. Santini JR.	17648-0027	7164

TITLE OF INVENTION: MEDICAL DEVICE WITH CONTROLLED RESERVOIR OPENING

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	$1510	$300	$0	$1810	03/23/2011

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PTOL-85 (Rev. 08/07) Approved for use through 08/31/2010.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail **Mail Stop ISSUE FEE**
Commissioner for Patents
P.O. Box 1450
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

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Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

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nonprovisional	NO	$1510	$300	$0	$1810	03/23/2011

EXAMINER	ART UNIT	CLASS-SUBCLASS
VU, QUYNH-NHU HOANG	3763	604-890100

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

(1) the names of up to 3 registered patent attorneys or agents OR, alternatively,

(2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____

2 _____

3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. The following fee(s) are submitted:

❑ Issue Fee

❑ Publication Fee (No small entity discount permitted)

❑ Advance Order - # of Copies _____

4b. Payment of Fee(s): **(Please first reapply any previously paid issue fee shown above)**

❑ A check is enclosed.

❑ Payment by credit card. Form PTO-2038 is attached.

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. **Change in Entity Status** (from status indicated above)

❑ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27.

❑ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 1705 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 1705 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	10/783,897	SANTINI ET AL.	
	Examiner	Art Unit	
	QUYNH-NHU H. VU	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *09/28/10*.

2. ☒ The allowed claim(s) is/are *55-76,85,94 and 97-102*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Quynh-Nhu H. Vu/
Examiner of Art Unit 3763

EXAMINER'S AMENDMENT

An examiner's amendment is based on BPAI (Board of Patent Appeals and Interferences) on 09/28/10, claims

Therefore, claims 1-54, 77-84, 86-93, 95-96, 103 have been cancelled; claims 85 and 94 have been rewritten as following:

Listing of Claims:

1-54. (Canceled).

55. (Previously presented). An implantable medical device for the controlled release of drug molecules comprising:

a substrate; at least two reservoirs in the substrate;

release system disposed in the reservoirs, the release system comprising drug molecules for release; and discrete metal reservoir caps positioned over or within openings in the reservoirs, wherein release of the drug molecules from the device is activated by disintegration of the reservoir cap and the disintegration of the reservoir cap is actively controlled.

56. (Previously presented). The device of claim 55, wherein the substrate is comprised of two or more substrate portions bonded together.

57, (Previously presented). The device of claim 56, wherein the substrate comprises an upper substrate portion adjacent the reservoir cap and a lower substrate portion distal the reservoir cap.

58. (Previously presented). The device of claim 57, wherein a reservoir section in the upper substrate portion is in communication with a reservoir section in the lower substrate portion, the two reservoir sections forming a single reservoir.

59. (Previously presented). The device of claim 57, wherein the reservoir section in the lower substrate portion has a volume that is greater than the volume of the reservoir section in the upper substrate portion.

60. (Previously presented). The device of claim 57, wherein the lower substrate portion is provided with an internal reservoir cap interposed between a reservoir section of the upper substrate portion and a reservoir section of the lower substrate portion, wherein release of the molecules from the

reservoir section in the lower substrate portion is controlled by diffusion through or disintegration of the internal reservoir cap.

61. (Previously presented). The device of claim 60, wherein the internal reservoir cap is disintegratable, so that the two reservoir sections become a single reservoir upon disintegration of the internal reservoir cap.

62. (Previously presented). The device of claim 60, wherein the reservoir section of the lower substrate portion contains molecules different in quantity, type, or both quantity and type, from the molecules contained in the reservoir section of the upper substrate portion.

63. (Previously presented). The device of claim 55, wherein disintegration of the reservoir cap is activated by application of" electrical energy through the reservoir cap.

64. (Previously presented). The device of claim 63, wherein at least one reservoir cap is an anode, and the device further comprises a cathode, a power source, and electrical circuitry means for application of an electric potential between the cathode and anode effective to disintegrate the reservoir cap.

65. (Previously presented). The device of claim 55, wherein the release system further comprises at least one matrix material, excipient, or combination thereof.

66. (Previously presented). The device of claim 55, wherein the release system further comprises at least one biodegradable or bioerodible polymeric material.

67. (Previously presented). The device of claim 55, wherein the drug molecules comprise anesthetics, vaccines, chemotherapeutic agents, metabotites, immunomodutators, antioxidants, antibiotics, and ion channel regulators, or hormones.

68. (Previously presented). The device of claim 55, wherein the disintegration of at least one of the reservoir caps is controlled by a signal from a biosensor or by a preprogrammed microprocessor.

69. (Previously presented). A microchip device for the controlled release of drug molecules comprising:

a substrate;

at least two reservoirs in the substrate, wherein each reservoir has at least one opening defined in the substrate;

release system disposed in the reservoirs, the release system comprising drug molecules for release; and at least two discrete electrically conductive reservoir caps, each reservoir cap closing off the opening defined by a respective reservoir,

wherein release of the drug molecules from the device is activated by disintegration of the reservoir cap by direct application of an electrical potential through the reservoir cap.

70. (Previously presented). The device of claim 69, wherein the substrate is comprised of two or more substrate portions bonded together.

71. (Previously presented). The device of claim 69, wherein at least one reservoir cap is an anode, and the device further comprises a cathode, a power source, and electrical circuitry means for application of an electric potential between the cathode and anode effective to disintegrate the reservoir cap.

72. (Previously presented). The device of claim 69, wherein the release system in at least one of the reservoirs differs in quantity, type, or both quantity and type, from the release system in at least one other of the reservoirs.

73. (Previously presented). The device of claim 69, wherein the release system further comprises at least one matrix material, excipient, or combination thereof.

74. (Previously presented). The device of claim 69, wherein the release system fin'ther comprises at least one biodegradable or bioerodible polymeric material.

75. (Previously presented). The device of claim 69, wherein the reservoir caps are formed of a metal film.

76. (Previously presented). The device of claim 70, wherein the drug molecules comprise anesthetics, vaccines, chemotherapeutic agents, metabolites, immunomodulators, antioxidants, antibiotics, and ion channel regulators, or hormones.

77-84 (Canceled).

85. (Currently amended). ~~The device of claim 77~~ A medical device comprising: a substrate;

at least two discrete reservoirs provided in spaced positions across at least one surface of the substrate;

discrete reservoir caps covering the at least two reservoirs; and

control circuitry for selectively disintegrating the reservoir caps to open the reservoirs; wherein the reservoir caps comprise a metal film.

86-93 (Canceled).

94. (Currently amended). ~~The device of claim 91~~ A device for use in medical diagnostics comprising: a substrate;

at least two discrete reservoirs provided in spaced positions across at least one surface of the substrate;

a diagnostic reagent disposed in the reservoirs; discrete reservoir caps covering the at least two reservoirs; and control circuitry for selectively disintegrating the reservoir caps to open the reservoirs; wherein the reservoir caps comprise a metal film.

95-96 (Canceled).

97. (Previously presented). A medical device comprising: a substrate;

at least two discrete reservoirs provided in spaced positions across at least one surface of the substrate;

discrete reservoir caps covering the at least two reservoirs; and

control circuitry for selectively disintegrating the reservoir caps to open the reservoirs,

wherein the reservoir cap disintegration comprises dissolving into solution, or forming soluble ions or oxidation compounds, upon application of an electric potential generated by the control circuitry.

98. (Previously presented). The medical device of claim 97, wherein the control circuitry comprises a cathode and a power source, wherein at least one reservoir cap is an anode, and wherein application of an electric potential between the cathode and anode causes at least one of the reservoir caps to disintegrate.

99. (Previously presented). The device of claim 97, wherein the reservoirs comprise molecules useful in medical diagnostics.

100. (Previously presented). The device of claim 99, wherein the molecules comprise a diagnostic reagent.

101. (Previously presented). The device of claim 97, wherein the reservoirs comprise drug molecules.

102. (Previously presented). The device of claim 97, wherein the reservoirs are microfabricated, at least one of the reservoirs contains drug or diagnostic molecules, and the device is adapted for implantation into a patient.

103. (Cancelled).

Allowable Subject Matter

Claims 55-76, 85, 94, 97-102 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to QUYNH-NHU H. VU whose telephone number is (571)272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

/Quynh-Nhu H. Vu/
Examiner, Art Unit 3763